

Exhibit E

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Absorbable Polyglactin Mesh for Retropubic Sling Operations in Female Urinary Stress Incontinence

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Key Words. Polyglactin mesh · Sling operations · Stress incontinence

Abstract. Mesh of absorbable polyglactin 910 instead of human tissues or nonabsorbable synthetic materials was utilized for retropubic sling procedures in 21 women with urinary stress incontinence. The patients have been observed for a period ranging from 4 to 14 months. 20 of them are continent while there was 1 relapse after 2 months. The post-operative complications were minimal, and there has been no instance of foreign body reaction.

Several retropubic sling procedures, using either human tissue or meshes of nonabsorbable synthetic materials, have been described for treatment of urinary stress incontinence (USI) in women. After use of the patient's own tissues, a sore donor place and complications such as hernia formation have been observed. Nonabsorbable synthetic meshes have been held responsible for laceration of the urethra or the bladder [10], as well as for foreign body reactions [13].

With this in mind, a mesh of an absorbable synthetic material, polyglactin 910, has been tried for the first time in this context.

Material and Methods

21 women with USI, consecutively operated at the Department of Obstetrics and Gynecology, Huddinge University Hospital, in 1981, constitute the basis of this report. As shown in table I, the age of the subjects ranges from 31 to 70 years. 3 of them had a previous operation for USI.

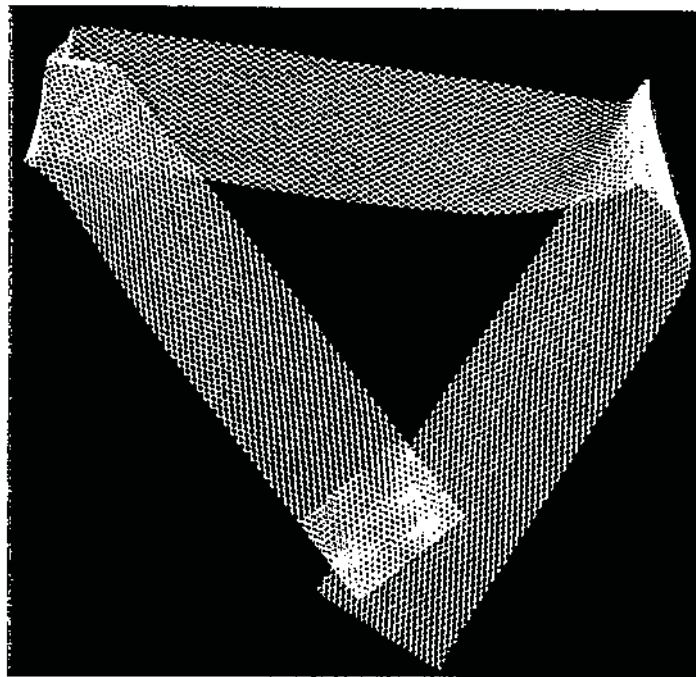


Fig. 1. Mesh of polyglactin used for sling.

Table I. Distribution of age of patients

Age in years	Number of patients
31-40	2
41-50	8
51-60	6
61-70	5

On the basis of history, physical examination and urologic investigations, including cystometrographic studies, all the 21 women were considered to have a pure USI. Women with complicating urgency incontinence, like those with an actual urinary tract infection (positive routine culture on admission) were excluded from the study.

All the patients underwent a suburethral sling procedure. The material of the sling was a suture mesh of polyglactin 910 (Vicryl-Ethicon) sized 30×3 cm (fig. 1). Each filament had a diameter of about 0.1 mm, and the pore size was about 1×1 mm (fig. 2).

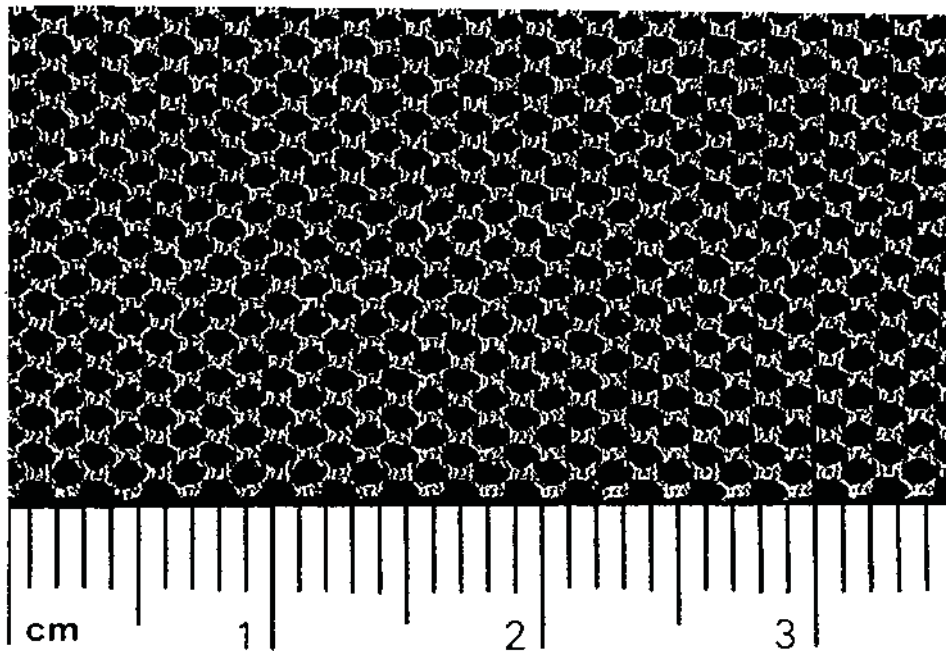


Fig. 2. Detail of mesh.

Operative Procedure

The patient was placed in the dorsal lithotomy position in order to provide access to the vagina and the lower abdomen at the same time.

With a Foley catheter placed in the bladder a transversal incision was made below the external urethral meatus. The anterior vaginal wall was freed from the urethra and the base of the bladder. Through the areolar plane normally separating the vagina from the bladder, a blunt dissection was made into the retropubic area. With a finger passed behind the pubic bone a retropubic tunnel was created on each side, as close to the urethra as possible, up to the external rectus aponeurosis, exposed by an abdominal incision. This was made through the skin, about 3 cm above the symphysis. The ends of the polyglactin mesh were brought from below via the retropubic tunnels and pierced through the external rectus aponeurosis with the aid of a long curved clamp (fig. 3). The belly of the polyglactin strip was applied to the undersurface of the vesicourethral junction. This was identified by traction of the Foley catheter. The abdominal ends of the polyglactin sling were united medially and clamped under moderate tension. A series of coughs was provoked. If there was still leakage of urine, the sling was stretched till tightness was reached. The ends of the sling were united medially by a square knot.

The bladder was drained by a Foley catheter via a suprapubic trocar cystotomy, and the catheter was attached to a closed drainage system. The abdominal incision was closed with drainage.

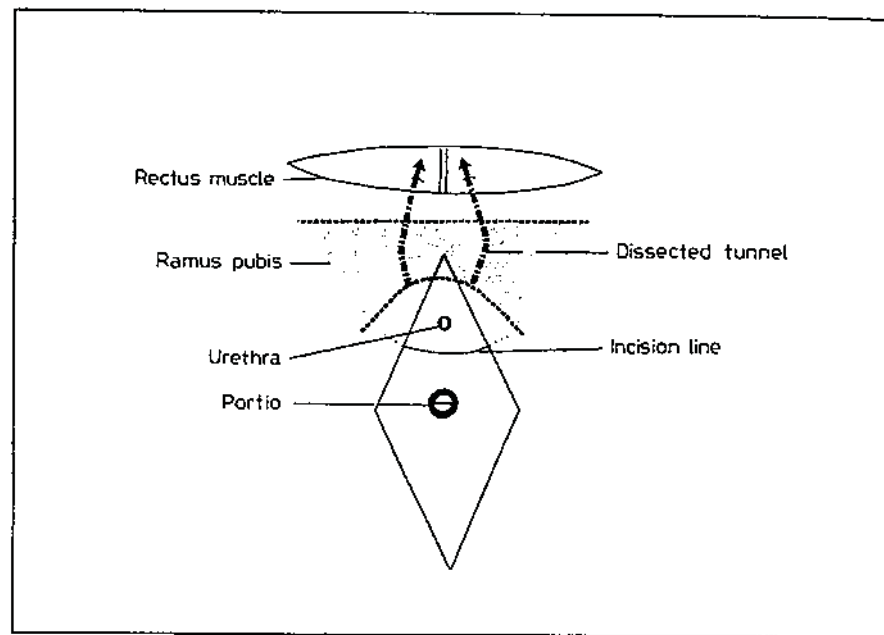


Fig. 3. Principles of operative procedure.

Results

All the 21 patients were followed up from 5 to 14 months. 20 of them were cured of incontinence. This implied that there was no symptom of urinary leakage nor could loss of urine be demonstrated with stress in the lithotomy or standing position. In 1 subject there was a relapse of the USI after 2 months. The procedures were well tolerated by all the women.

Occurrence of postoperative urinary retention is an unavoidable problem after all sling procedures. In this material the average time needed for reestablishment of a satisfactory voiding pattern was 14 days.

In 1 subject there was a continued leakage of urine immediately after the operation (unsatisfactory operative continence test, because of very heavy general anesthesia, resulting in weak coughs). 1 week after the primary operation the sling was revised. The square knot was opened and the sling was stretched till strong coughs showed tightness of the bladder. The continued postoperative course was uneventful even in this patient, and the continence was lasting.

Discussion

In treatment of female USI with sling procedures there has long [10] been a need for a material which would offer the advantages of synthetic ones to simplify the procedure but which at the same time would be absorbable.

In recent years, absorbable synthetic sutures of polyglactin 910, a copolymer of derivatives of glycolic and lactic acid, have been widely available. They are virtually absorbed within 3 months [4] and remain as stable in contaminated wounds [3]. Breakdown and absorption is considered to be through hydrolysis, independent of cellular or enzyme activity [12]. Polyglactin does not seem to inhibit or stimulate bacterial growth [11].

Lately, mesh of polyglactin 910 became available, and its behavior has been studied in animals [2] and in man [11].

In this study the polyglactin mesh was found easy to handle for sling procedures. The cure rate was 95% which is well comparable with those of others. In six studies [1, 6-8, 10, 13], selected at random and including 322 sling procedures, the cure rate was 75-88%. According to earlier experience [5, 8-10] the therapeutic results are not supposed to change considerably after an observation period of 6 months.

An advantage of the polyglactin mesh was to permit a modification of the sling shortly after the primary operation.

The use of nonabsorbable materials for sling procedures has been held responsible for laceration of the urethra or the bladder [10], as well as for foreign body reactions in the host [13]. Polyglactin mesh did not seem to convey any such complications.

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